UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to:	)	
Tonya Brand, 1:14-cv-6018-RLY-TAB	)	

ENTRY ON THE COOK DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S FAILURE TO WARN CLAIMS

Cook Incorporated, Cook Medical LLC (f/k/a Cook Medical Incorporated), and William Cook Europe APS (collectively "the Cook Defendants" or "Cook") develop, manufacture, sell, and distribute medical devices for use in medical applications throughout the United States and the world. The medical devices at issue in this litigation are the Cook Defendants' Inferior Vena Cava Filters, most notably the Günther Tulip® Vena Cava Filter and the Cook Celect® Vena Cava Filter. These devices are used for the prevention of pulmonary embolism by trapping blood clots as they travel through the inferior vena cava. The Plaintiffs in this multi-district litigation case allege that the filters are prone to, *inter alia*, tilt, migrate, fracture, and perforate the inferior vena cava, causing them personal injuries.

This present bellwether case is brought by Plaintiff Tonya Brand. Her claims against the Cook Defendants include strict liability and negligent failure to warn, strict liability and negligent design defect, negligent manufacturing, negligence *per se*, breach of warranty, loss of consortium, and punitive damages.

On July 20, 2018, the Cook Defendants filed the present motion for summary judgment on all claims. Plaintiff failed to respond to the Cook Defendants' motion with respect to her breach of warranty, negligent manufacturing, and loss of consortium claims. Accordingly, the court **GRANTS** Cook's motion as to those claims. *Bonte v. U.S. Bank N.A.*, 624 F.3d 461, 466 (7th Cir. 2010) (noting the failure to respond to an argument results in waiver). In addition, the court **GRANTS** Cook's motion with respect to Plaintiff's negligent and strict liability failure-to-warn claims. The basis for those rulings is set forth below.

I. Background

Plaintiff suffers from a number of ailments, including spinal disc degeneration. (Filing No. 8660-1, History and Physical Report dated 2/24/2009). Due to her worsening lumbar disc disease, Plaintiff was scheduled for spinal-fusion surgery. (*Id.*). Her spinal surgeon, Dr. Thomas Morrison, sent her to Dr. Mark Rheudasil, a vascular surgeon, before her surgery so that Dr. Rheudasil could evaluate her. He recommended an IVC filter for Plaintiff for a number of reasons, including that Plaintiff: (1) was facing a [b]ig spine surgery," (2) was slightly overweight, (3) had a history of DVT, (4) had multiple abdominal surgeries that would complicate the spinal surgery that she was about to have,

and (5) would be on bedrest for a period of time. (Filing No. 8660-3, Deposition of Dr. Mark Rheudasil at 48).

On March 19, 2009, Dr. Rheudasil implanted a Celect IVC filter into Plaintiff. (Filing No. 8660-4, Rheudasil Operative Report dated 3/19/2009; Rheudasil Dep. at 32; Filing No. 8660-5, Morrison Operative Report dated 3/19/2009). Immediately after the filter was inserted, Dr. Rheudasil performed a vascular surgery to "open up" plaintiff's abdomen so that Dr. Morrison could operate on her spine. (*Id.*). Dr. Morrison then performed the spinal-fusion surgery. (*Id.*).

In May 2011, Plaintiff began to experience pain on the inside of her right thigh. (Filing No. 8660-10, Deposition of Tonya Brand at 113). She had an ultrasound the following day which indicated "there was something in [her] leg." (*Id.* at 114). In mid-June 2011, Plaintiff testified that she was at home and noticed something protruding out of her thigh. (*Id.* at 116-17). She pulled it out and knew it was part of her IVC filter. (*Id.* at 117).

Soon thereafter, Dr. Rheudasil ordered a full body scan of Plaintiff. (*Id.* at 119). The scan indicated that the filter had fractured and that another strut had migrated to an area near Plaintiff's spine. (*Id.*).

On July 14, 2011, Dr. Rheudasil attempted to retrieve the filter percutaneously but was unsuccessful. (Filing No. 1, Compl. ¶ 29). Dr. Rheudasil and Plaintiff elected to leave the filter in place until October 22, 2015, at which time Dr. Rheudasil removed it through open surgery. (Filing No. 8660-11, Operative Report dated 10/22/2015).

All other facts material to the disposition of this claim will be addressed *infra.*

II. Discussion

Plaintiff contends that the Cook Defendants failed to provide adequate warnings regarding the risks associated with the Celect IVC filter and that she was injured as a result. The parties agree that Georgia law applies to Plaintiff's claims.

A. Failure to Warn

To establish a failure to warn claim under Georgia law[1], a plaintiff must establish that: (1) the defendant had a duty to warn, (2) the defendant breached that duty, and (3) the breach was the proximate cause of the plaintiff's injuries. *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (citing *Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1362 (N.D. Ga. 1999) (holding proximate cause is an element of plaintiff's case whether proceeding under a strict liability or negligence theory)). "Under Georgia's learned intermediary doctrine, a medical device manufacturer 'does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.'" *In re Mentor ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F.Supp.2d 1348, 1365 (M.D. Ga. 2004) (quoting *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003)). The manufacturer's warnings to the doctor "'must be adequate or reasonable under the circumstances of the case.'" *Id*. (quoting *McCombs*,

[1] Under Georgia law, failure to warn claims premised on strict liability or negligence are separate claims but are often analyzed together. *Dietz*, 598 F.3d at 815 (addressing strict liability and negligent failure to warn claims together); *see also Wells by Maihafer v. Ortho Pharm. Corp.*, 615 F.Supp. 262, 296 (N.D. Ga. 1985) (noting the elements of strict liability and negligent failure to warn claims "are essentially the same"). Accordingly, the court will analyze Plaintiff's failure to warn claims together.

587 S.E.2d at 595)). If the warning is adequate, the court's analysis ends, and the plaintiff cannot recover. *Dietz*, 598 F.3d at 816. If, however, the warning is inadequate or presumed to be inadequate, the plaintiff must establish that the inadequate warning proximately caused her injuries. *Id*. "[W]here 'a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that . . . the causal link is broken and the plaintiff cannot recover.'" *Id*. (quoting *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272 (11th Cir. 2002)).

The Celect's Instructions for Use ("IFUs") list the following as "potential adverse events:

- Damage to the vena cava
- Pulmonary embolism
- Filter embolization
- Vena cava perforation
- Vena cava occlusion or thrombosis
- Hemorrhage
- Hematoma at vascular access site
- Infection at vascular access site
- Death

(Filing No. 8657-1, IFU for Cook Celect Filter Set). Plaintiff argues the IFU was inadequate because it does not mention tilt, progressive perforation, or fracture;

it did not inform doctors that the clinical study discussed in the IFU – the OUS Study—contained inaccurate and misleading data; and it did not inform doctors that the Celect, unlike the Tulip, did not have perforation limiters—a design change, Plaintiff argues, which caused the Celect to have a much higher rate of perforation and fracture than the Tulip.

At the time of Plaintiff's IVC filter placement, Dr. Rheudasil was aware of the risks associated with conical-shaped IVC filters like the Celect, including the risk of tilt, perforation, migration, and fracture. (Rheudasil Dep. at 60-62). He testified that these risks "were not unique to the Celect filter." (*Id.* at 63 ("I know of no complication unique to the Celect filter.")). His knowledge[2] of these risks was not based on the Celect IFU or any other Cook document[3]; rather, it was based on his education, training, and

[2] Dr. Rheudasil also testified that he typically reads the IFUs of the products he uses, but he could not recall whether he read the Celect IFU. (Rhuedasil Dep. at 207). If he could not recall reading the Celect IFU, he could not have relied upon the warnings and other information set forth in it.

[3] Plaintiff argues that although Dr. Rheudasil may have known about the risks of IVC filters in general, he was not aware of the risks unique to the Celect, including its alleged "significant propensity to tilt, perforate, and fracture" as evidenced by Cook internal documents. To establish his lack of knowledge of the alleged risks associated with the Celect, Plaintiff relies on Dr. Rheudasil's answers to a series of hypothetical questions that assume the Celect is not a safe product. In answer to those questions, he testified that the information would have been material to the Celect's risks and benefits. (*Id.* at 155-56 ("Q: Were you ever told by the sales reps at Cook that the Celect filter was less safe than the Tulip? A: No. Q: Had you known either one of those things, would that have given you information of materiality? A: Hypothetically, yes."); *see also id.* at 157-58 ("Q: Okay. If you had been made aware by Cook of any material differences in safety between the Celect and the Tulip, would you have disclosed those differences to your patient, Tonya Brand? A: No, I would have just used the safer filter.")). This testimony proves only that if Dr. Rheudasil were to assume the Celect was unsafe, he would choose a safer product for his patients, as *any* doctor would. It does *not* establish, however, that Dr. Rheudasil would have interpreted Cook's internal documents the same way that Plaintiff does.

experience. (*Id*. at 67 ("Q: Was your knowledge of the risks of placing a vena cava filter in [Plaintiff] based on anything other than your training, education, and experience? A: No.")).

Moreover, Dr. Rheudasil testified that he continued to use the Celect filter even after Plaintiff's 2011 filter fracture. (*Id*. at 97; *see also id*. (testifying he "had no problem using [the Celect]" in terms of its safety and efficacy)). In fact, nothing about Plaintiff's experience from 2009 to 2015 caused him to change his mind about using IVC filters in general or the Celect in particular. (*Id*. at 97-98). In the face of this devastating testimony, Plaintiff fails to raise a genuine issue of material fact on the proximate causation element of Plaintiff's negligent and strict liability failure to warn claims.

B. Post-Sale Duty to Warn

Under Georgia law, the duty to warn is "a continuing one and may arise 'months, years, or even decades after the date of the first sale of the product.'" *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1218 (11th Cir. 1999) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)). Plaintiff argues Cook had a post-sale duty to warn Dr. Rheudasil of the Celect's propensity to perforate and fracture. Had Cook done so, she continues, Dr. Rheudasil "potentially could have removed the filter before it fractured and pieces migrated throughout [Plaintiff's] body." (Filing No. 9416, Response at 23; *see also* Filing No. 9590, Response to New Post-Sale Warning Argument at 8 ("[I]t is

almost certain that if warned by Cook he would have called[4] [Plaintiff] and told her to come in for retrieval.")).

Plaintiff's argument is based on speculation. She has offered no testimony from Dr. Rheudasil or any other treating physician suggesting that they would have retrieved Plaintiff's filter earlier (or altered their treatment of Plaintiff) had they received additional warnings post-implantation. Indeed, the evidence suggests that Plaintiff's treating physicians, including Dr. Rheudasil, would not have retrieved Plaintiff's filter earlier (or changed Plaintiff's treatment) based on any additional post-placement warning by Cook. As noted above, Dr. Rheudasil continued to use the Celect even after Plaintiff's filter fractured and had no problem doing so. (Rheudasil Dep. at 97). In fact, he believed it was "probably still offering her some pulmonary embolus protection," particularly when her knee was replaced in October 2012. (Rheudasil Dep. at 190-91). Accordingly, Plaintiff fails to raise a genuine issue of material fact that any post-implant failure to warn caused her injuries. *See In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, MDL No. 4:08-MD-2004 (CDL), 2015 WL 5722799, at *4 (M.D. Ga. Sept. 9, 2015) (finding plaintiff failed to establish that any post-sale failure to warn caused her injuries).

III. Conclusion

The undisputed evidence reflects that Dr. Rheudasil (1) did not rely on the Celect

[4] For reasons unknown, Plaintiff did not come back for her retrieval appointment. (Rheudasil Dep. at 74-75 ("I don't know what many of the myriad possibilities are as to why she didn't come back to have it retrieved.")).

IVC filter's IFU, (2) already knew at the time of Plaintiff's implant about all of the complications Plaintiff experienced, and (3) would not have treated Plaintiff any differently even knowing now the complications that she actually suffered. Therefore, Plaintiff is unable, as a matter of law, to establish causation in her strict liability and negligent failure to warn claims. Accordingly, the Cook Defendants' Motion for Summary Judgment (Filing No. 8649) on Plaintiff's negligent failure to warn claim is **GRANTED**. The Cook Defendants' motion is also **GRANTED** on Plaintiff's breach of warranty, negligent manufacturing, and loss of consortium claims.

SO ORDERED this 5th day of December 2018.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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